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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,500	03/18/2005	Silvia Berlanga de Moraes Barros	ABARR.0101	4409

22858 7590 01/09/2009
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EXAMINER	
TATE, CHRISTOPHER ROBIN	
ART UNIT	PAPER NUMBER
1655	
MAIL DATE	DELIVERY MODE
01/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,500	DE MORAES BARROS ET AL.	
	Examiner	Art Unit	
	Christopher R. Tate	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24,27 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24, 27, and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 03 November 2008 is acknowledged and has been entered.

Claims 24, 27, and 28 have been presented and examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24, 27, and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 24 and 28 recite various numerical range limitations regarding the amounts of elements a) through c) which are not supported by the instant specification (i.e., the Examiner could not find support for the narrower ranges instantly claimed, nor did Applicants particular point to such support within the instant specification). In other words, the instant specification does not support the following numerical percentage ranges:

- a range from 0.001 to 2.0% of carboxymethylcellulose (i.e., the specification appears to only support a range from 0.01 to 10.0% of this element).

- a range from 5.0 to 20.0% of propylene glycol (i.e., the specification appears to only support a range from 0.001 to 50.0% of this element).

- a range from 0.1 to 1.0% of methylparaben (i.e., the specification appears to only support a range from 0.001 to 3.0% of this element).

Applicant is required to cancel the new matter in the reply to this Office Action - or alternatively, to particularly point to adequate support for the above discussed claim limitations, in response to this Office action.

Claim Rejections - 35 USC § 103

Claims 24, 27, and 28 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ropke et al. (Free Radical Biol. Med., Vol 33, Issue 2, Abstract #527, 15 July 2002) and Ropke et al. (Annals of the 14th National Cosmetology Congress of the Brazilian Cosmetology Assoc, 2000 - including entire English Translation of this document) in view of Wheeler (US 6,165,479) and, if necessary, the admitted state of the art - for the reasons set forth in the previous Office action which are restated below.

The two cited Ropke et al. references each beneficially teach a topical gel compositions having strong therapeutic antioxidant activity which comprises an extract of *Pothomorphe umbellata*, whereby the gel compositions comprises 4-nerolidylcatechol (on the basis of the *Pothomorphe umbellata* extract). In addition, the second Ropke et al. reference (2000) discloses a topical compositions presented in a gel form (i.e., within diadermine - an oil/water emulsion) comprising an extract of *Pothomorphe umbellata*, whereby the topical compositions comprises 0.2%, 0.05, 0.1, 0.2, and 2% (p/p) of 4-nerolidylcatechol therein; and further that the dry extract

contains 2.35% of 4-nerolidylcatechol therein (see, e.g., page 8 of English translation) - thus, apparently within the instantly claimed ranges therein. The cited Ropke et al. references also teach topically applying the gel compositions to the skin of hairless mice (see Abstract# S527 of first Ropke et al. reference; and entire English translation including pages 2-5, 7-9,13-14, 16, and final paragraph on page 18 of the second Ropke et al. reference) - e.g., as a photoprotective agent for treating skin cancer and/or aging. Neither of the Ropke et al. references expressly teaches providing the skin therapeutic *Pothomorphe umbellata* extract within a skin gel composition containing carboxymethylcellulose, propylene glycol, and methylparaben, as instantly claimed.

Wheeler beneficially teaches that carboxymethylcellulose, propylene glycol, and methylparaben are well known conventional ingredients within skin therapeutic compositions such as skin gels, including those containing an antioxidant therein (see entire reference including col 2, line 58 - col 4, line 67). Further, as readily admitted by Applicants, the instantly claimed dermocosmetic composition can be prepared in accordance with prior art methods for topical use - such as one containing carboxymethylcellulose, propylene glycol, and methylparaben (see, e.g., page 11, lines 1-5).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate the *Pothomorphe umbellata* extract preparation having strong therapeutic antioxidant activity as taught by each of the Ropke et al. references into a conventional skin therapeutic formulation (e.g., as an effective antioxidant) - including a skin gel, containing the commonly-employed skin care ingredients carboxymethylcellulose, propylene glycol, and methylparaben therein based upon the beneficial teachings provided by Wheeler, as well as (if necessary) the admitted state of the prior art, with respect to their well

known conventional use therein, as discussed above. Accordingly, the adjustment of this and other types of conventional working conditions (e.g., determining an appropriate amount range of such conventional ingredients therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole was clearly *prima facie* obvious over the references (and, if necessary, the admitted state of the art) especially in the absence of clear and convincing evidence to the contrary.

Claims 24, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchiyama et al. (JP 2001122763 - full computer-assisted English translation enclosed) in view of Barros et al. (Ciencia e Cultura, 1996) and Desmarchelier et al. (Planta Med, 1997), and further in view of Wheeler (US 6,165,479) and, if necessary, the admitted state of the art - for the reasons set forth in the previous Office action which are restated below.

Uchimyama et al. beneficially teach a topical skin composition (e.g., in the form of a lotion, cream, etc.) comprising an extract of *Pothomorphe umbellata*.(including an alcoholic extract such as an ethanolic or methanolic extract - please note, as evidenced by Barros et al. and Desmarchelier et al., such an alcoholic extract would inherently comprise the naturally occurring compound 4-nerolidylcatechol) as an active skin therapeutic ingredient therein (e.g., useful against skin aging caused by ultraviolet rays among other therapeutic effects), as well as

topically applying such a composition to the skin. Uchimyama et al. also beneficially teach that the extract composition has antioxidant activity (i.e., oxygen-eliminating ability) - such as instantly disclosed (see entire English translation including paragraphs [0007] - [0016], [0021], [0028], [0034]-0035], [0037], and Tables).

The Barros et al. and Desmarchelier et al. references each beneficially teach a composition comprising an alcoholic (ethanolic - Barros et al; methanolic - Desmarchelier et al) extract of *Pothomorphe umbellata* - whereby the extracts demonstrate strong antioxidant activity (such as instantly disclosed) which contain the compound 4-nerolidylcatechol - apparently within the instantly claimed percentage range (as best understood) - therein (see entire documents including *Abstract* and *Materials and Methods*).

None of the above references, including Uchimyama et al., expressly teach providing the skin therapeutic *Pothomorphe umbellata* extract within a skin gel composition - including one containing carboxymethylcellulose, propylene glycol, and methylparaben, as instantly claimed.

Wheeler beneficially teaches that carboxymethylcellulose, propylene glycol, and methylparaben are well known conventional ingredients within skin therapeutic compositions such as skin gels, including those containing an antioxidant therein (see entire reference including col 2, line 58 - col 4, line 67). Further, as readily admitted by Applicants, the instantly claimed dermocosmetic composition can be prepared in accordance with prior art methods for topical use - such as one containing carboxymethylcellulose, propylene glycol, and methylparaben (see, e.g., page 11, lines 1-5).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate an alcoholic (e.g., ethanolic or methanolic) extract of *Pothomorphe umbellata* within the skin therapeutic composition (having antioxidant activity) as taught by Uchimyama et al, especially since Uchimyama et al. beneficially teaches that ethanolic and methanolic solvents are effective solvents to employ, and Barros et al. and Desmarchelier et al. beneficially teaches that such alcoholic solvents provide a *Pothomorphe umbellata* extract having strong antioxidant activity (in addition, it should again be noted that, as evidenced by Desmarchelier et al., such an alcoholic extract would inherently comprise the naturally-occurring compound 4-nerolidylcatechol therein). It would further have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate such a *Pothomorphe umbellata* extract into a conventional skin therapeutic formulation (e.g., as an effective antioxidant) - including a skin gel, containing the commonly-employed skin care ingredients carboxymethylcellulose, propylene glycol, and methylparaben therein based upon the beneficial teachings provided by Wheeler, as well as (if necessary) the admitted state of the prior art, with respect to their well known conventional use therein, as discussed above. Accordingly, the adjustment of this and other types of conventional working conditions (e.g., determining an appropriate amount range of such ingredients therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole was *prima facie* obvious over the references (and, if necessary, the admitted state of the art) especially in the absence of clear and convincing evidence to the contrary.

Applicants' arguments over the art rejections above have been carefully considered but are not deemed to be persuasive of error in the rejections.

Applicants argue that although the Examiner is correct in his assertion that none of the cited references "expressly teach providing the skin therapeutic *Pothomorphe umbellata* extract within a skin gel composition containing carboxymethylcellulose, propylene glycol, and methylparaben, as instantly claimed", the Applicant maintains that one of the cited Ropke references - within the first USC 103 rejection above (i.e., Annals of the 14th National Cosmetology Congress of the Brazilian Cosmetology Assoc, 2000) does not teach a topical composition in a gel form as previously suggested by the Examiner - i.e., the Examiner indicated that the 2000 Ropke reference discloses topical compositions presented within diadermine - an oil/water emulsion. That is, Applicants argue that emulsions are unstable and thus do not form spontaneously, whereas gels are most liquid in composition exhibiting densities similar to liquids and having structural coherence. However, without an express definition within the instant specification defining such a "gel composition", the Examiner maintains that the water/oil emulsion taught by the 2000 Ropke reference reasonably reads upon a "gel composition" as instantly claimed - whereby the composition comprises an extract of *Pothomorphe umbellata* containing 0.2%, 0.05, 0.1, 0.2, and 2% (p/p) of 4-nerolidylcatechol therein.

Applicants further argue that although Wheeler teaches that carboxymethylcellulose, propylene glycol, and methylparaben are well known conventional ingredients within skin therapeutic compositions such as skin gels, the specific gel composition as instantly claimed would not have been obvious in view of the state of the art including because determining the appropriate amount range and specific ingredients so as to provide the appropriate skin

penetration of 4-nerolidylcatechol was not a matter of routine optimization (i.e., would lead to virtually endless experimentation) - including based upon the data shown within the instant specification and figures concerning the passage/penetration of this compound into/through the skin, etc. However, for the reasons fully set forth above under both USC 103 rejections, the adjustment of these types of conventional working conditions (e.g., determining appropriate amount ranges of these types of ingredients - which are well-recognized and commonly-employed within skin gel therapeutic compositions) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

With respect to other generalized statements by Applicants regarding the criteria for establishing a *prima facie* case of obviousness, Applicants have argued and discussed some of the references individually without clearly addressing the combined teachings (further, please note that some of the cited references within the art rejections above, including the admitted state of the art discussed therein, were not addressed in Applicants arguments). It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which make up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the references.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher R. Tate/
Primary Examiner, Art Unit 1655